

**REMARKS**

**I. Status of the Claims**

Claims 23-42 are pending in this application. Claims 39-42 stand withdrawn from further consideration under 37 C.F.R. § 1.142(b). Claims 23-33 stand rejected under 35 U.S.C. § 103(a). Claims 34-38 stand rejected under 35 U.S.C. § 112, second paragraph. Claim 34 has been amended. Support for the amendment can be found, for example, on page 6, lines 25-28, of the as-filed specification. No new matter is added by this amendment.

**II. The Claims Are Not Obvious**

The Examiner maintains the rejection of claims 23-33 under 35 U.S.C. § 103(a) as allegedly being obvious over Zanta *et al.* in view of Neidigh *et al.* According to the Examiner, it would have been obvious to one of ordinary skill in the art at the time this application was filed to modify the method for functionalization of polyethyleneimine as allegedly taught by Zanta *et al.* with the conditions for reductive amination allegedly taught by Neidigh *et al.* Office Action mailed January 14, 2003, at pages 5-6.

In response, Applicants argued, *inter alia*, that the cited references fail to provide a reasonable expectation of success in preparing functionalized polyalkyleneimines according to claim 23. Amendment filed August 12, 2003, at page 8.

In the Advisory Action mailed September 4, 2003, the Examiner asserted that Applicant's arguments regarding the expectation of success "do not take the place of evidence that the process for preparing functionalized polyalkyleneimines as taught by the combination of the Zanta *et al.* and Neidigh *et al.* references would not be expected

to produce compounds having the same functional characteristics as the compounds produced by the methods recited in the currently examined claims."

Pursuant to 37 C.F.R. § 1.132, Applicants file concurrently herewith the Declaration of coinventor Jean Herscovici, Ph.D., which provides the evidence requested by the Examiner. According to Dr. Herscovici, one skilled in the art would not have had a reasonable expectation of success in using the method described by Neidigh to prepare the functionalized polyalkyleneimines claimed in the instant application. Dr. Herscovici explains that Neidigh discloses the preparation of N-methyl secondary amines from carbonyl compounds, i.e., aldehydes and ketones, not from hemiacetals as taught by the instant application. Declaration dated November 12, 2003, at paragraph 6. Because hemiacetals do not have a carbonyl group, one skilled in the art would not expect them to react with amines under the conditions disclosed by Neidigh. *Id.*, at paragraph 10. Dr. Herscovici states that, in particular, a polyhydroxylated hemiacetal (i.e., a carbohydrate) would not be expected to participate in the reaction described by Neidigh. *Id.* Dr. Herscovici notes that, in contrast to the Examiner's position, the acetals to which Neidigh refers are substituents of the aldehyde's "R" group, not participants in the reaction. *Id.*, at paragraph 12. Thus, Neidigh discloses that acetals *are not* converted into amines under his reaction conditions. *Id.*, at paragraph 13.

For the reasons above, Applicants respectfully request the reconsideration and withdrawal of the rejection of claims 23-33 under 35 U.S.C. § 103(a).

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### III. Th Claims Are Definit

The Examiner maintains the rejection of claims 34-38 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. According to the Examiner, "the metes and bounds of [the phrase "targeting element"] is vague and indefinite since [claim 34] does not indicate what the compound is targeting, and it does not define the structure of this element." Office Action mailed June 3, 2003, at page 4; see also Advisory Action mailed September 4, 2003 ("the specification as filed merely defines the targeting element in terms of its function, there is no structure defined in the specification as filed associated with said targeting element"). According to the Examiner, "[o]ne of ordinary skill in the art would not be reasonably apprised of the scope of the claimed invention, since neither the specification as filed nor the claims provides an adequate definition of the term "targeting element" as used in this context." *Id.*

According to the M.P.E.P., "[a] functional limitation is an attempt to define something by what it does, rather than by what it is (e.g., as evidenced by its specific structure or specific ingredients). There is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper." M.P.E.P. § 2173.05(g) citing *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971). In addition, the M.P.E.P. states that "[a] functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used." *Id.* That is, a functional limitation, like any other, satisfies the requirements of 35 U.S.C. 112, second paragraph if "those skilled in the art would understand what is claimed when the claim is read in light of the specification." See

*Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 U.S.P.Q.2d 1081, 1088 (Fed. Cir. 1986); *see also* M.P.E.P. § 2173.02.

Applicants have amended claim 34 to recite that that the targeting element "directs the transfer of a nucleic acid toward specific cell types, specific tissues, or specific cell compartments." The specification provides examples of eight classes of targeting elements: sugars, peptides, proteins, oligonucleotides, lipids, neuromediators, hormones, and vitamins. See Specification, page 8, lines 21-25. Within these classes, the specification provides at least eighteen specific targeting molecules. From the specification and from the language of claim 34, one skilled in the art would understand that a "targeting element" is any moiety "directs the transfer of a nucleic acid toward specific cell types, specific tissues, or specific cell compartments." The law requires no more to find that claim 34 (and claims 35-38, which depend therefrom) as amended is definite.

For the reasons above, Applicants respectfully request the reconsideration and withdrawal of the rejection of claims 34-38 under 35 U.S.C. § 112, second paragraph.

#### **IV. Conclusion**

In view of the foregoing amendment and remarks, Applicants respectfully request the continued examination of this application pursuant to 37 C.F.R. § 1.114, and the timely allowance of the pending claims. Should the Examiner feel that this application is not in condition for allowance, Applicants request that she contact the undersigned representative at 202-408-4185.

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Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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By:   
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